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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 10/556,937 | 10/31/2006 | Michael R. Costa | EX04-044C-US | 6980 |

63572 7590 10/12/2007
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| EXAMINER |
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GEBREYESUS, KAGNEW H

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| ART UNIT | PAPER NUMBER |
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1656

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| MAIL DATE | DELIVERY MODE |
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10/12/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/556,937

Applicant(s)

COSTA ET AL.

Examiner

Kagnew H. Gebreyesus

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 May 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-25 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-25 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- ☐ Notice of Informal Patent Application
- ☐ Other: _____

DETAILED ACTION

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions, which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I. Claims 1, 4, 5, 7 (11, 12, 16-19 partially) are drawn to a method of identifying a candidate PTEN pathway modulating agent comprising, providing an assay system comprising a MARK polypeptide with a candidate agent and comparing a test biased activity relative to a reference.

Group II- Claims 1, 8, 9, 10, (11, 12, 16-19 partially) are drawn to a method of identifying a candidate PTEN pathway modulating agent comprising, providing an assay system comprising a MARK nucleic acid with a candidate agent and comparing a test biased activity relative to a reference.

Group III- Claims 1-3, 6, (11, 12, 16-19 partially), are drawn to a method of identifying a candidate PTEN pathway modulating agent comprising, providing an assay system

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comprising contacting cultured cells comprising a MARK polypeptide with a candidate agent and comparing a test biased activity relative to a reference.

Group IV- Claims 13-15, (20-22 partially) are drawn to a method of modulating PTEN pathway in a cell or animal defective in PTEN function comprising contacting said cell with an agent that specifically binds a MARK polypeptide whereby PTEN function is restored.

Group V. Claims 20-22 partially are drawn to a method of modulating PTEN pathway in a cell or animal defective in PTEN function comprising contacting said cell with an agent that specifically binds a MARK nucleic acid.

Group VI. Claims 23-25 are drawn to a method of diagnosing a disease in a patient based on expression level of MARK.

The inventions listed as Groups I-VI do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

The technical feature in Claim 1 which links the inventions first mentioned in groups I is a method of identifying a candidate PTEN pathway modulating agent, wherein the activity of MARK polypeptide or nucleic acid is assayed in the presence or absence of a test agent.

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Drews et al. teach an assay wherein the activity of MARK is assayed in the presence or absence of protein phosphatase 2A (PP2A) which dephosphorylates MARK and inactivated it's ability to phosphorylate a peptide TR1 (see page 298, page 301 and figures). Thus the technical feature linking groups I is not a special technical feature as defined in Rule 13.2.

Furthermore, this application contains claims directed to more than one species of the generic invention in Group III. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1. Each of the parameters measures patentably distinct parameters. The species are as follows:

- (a) an apoptosis assay system,
- (b) a cell proliferation assay system
- (c) an angiogenesis assay system
- (d) a hypoxic induction assay system.

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims

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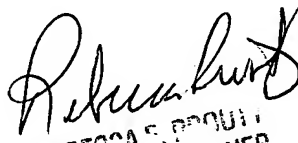
are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kagnew H. Gebreyesus whose telephone number is 571-272-2937. The examiner can normally be reached on 8:30am-5:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kathleen Kerr Bragdon can be reached on 571-272-0931. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

10-05-07
KGH


REBECCA E. PROULX
PRIMARY EXAMINER
GROUP 1656
1656

Kagnew H Gebreyesus
Examiner
Art Unit 1656

